MAY 17 2002

WUJIANG CITY HUA XIN MEDICAL APPLIANCE CO. LTD.

EAST OF TUN CUN, WUJIANG CITY, JIANGSU PROVINCE, P. R. OF CHINA, 215216
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PREMARKET NOTIFICATION
510(k) SUMMARY
As required by 21 CFR 807.92(c)

Date Summary Prepared: March 15, 2002

Submitter: Wujiang City Hua Xin Medical Appliance Co., Ltd.
East of Tun Cun
Wujiang City, Jiangsu Province, PR of China
Telephone: 011-86-512-3373566
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Contact Person: Mr. Liu Jin Xin, Factory Director

US Contact: Laura J. Thorne
Thorne Sales & Distributing, Inc.
10 Westmont Road
Candler, North Carolina 28715
Telephone: (828) 670-5464
Fax: (828) 670-8610

Name of Device: Holy Dragon Brand Acupuncture Needles for Single Use

Product Code: MQX

Classification: Class II

Common or Usual Name: Acupuncture Needles

510(k) Number: K021095

Substantial Equivalence:

The Holy Dragon Brand Acupuncture Needles are substantially equivalent in design, materials and performance to other acupuncture needle brands that were in commercial distribution before May 28, 1976. They are also equivalent to acupuncture needles which have been found to be substantially equivalent through the 510(k) premarket process. These are Holy Dragon K002910 (2/7/2001) and Holy Dragon K011247 (10/17/2001).

Description of Device:

The Holy Dragon Brand Acupuncture Needles are sterile disposable, surgical stainless steel with a spiral wound silver or copper handle that is mechanically attached. The needles are supplied individually blister sealed packaged with polypropylene insertion tubes and medical grade paper. They are sold in paper carton boxes in quantities of either 100 or 500 needles per box. Statements "For single use only," "Federal law restricts this device to sale by or on the order of qualified practitioners of acupuncture as determined by the States," "Pyrogen Free," and "made in China" are shown in box labeling.

Intended Use:

Holy Dragon Brand Acupuncture Needles are used to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States. They are not suitable for home use.

Comparison:

Holy Dragon Brand Acupuncture Needles have the same technological characteristics as the predicate devices identified before. They are manufactured in the same lengths and gauges (thickness); handle length and design (spiral wound mechanical attached) and packaging methods (single blister). The validation of sterilization method is the same and residues of ETO and derivates are according to the required regulations. The method of insertion in polypropylene guide tubes is the same use for the predicates.

Substantial equivalence is not based on an assessment of performance data.

Liu Jin Xin

Mr. Liu Jin Xin, Factory Director

May 09, 2002

Date

Acupuncture Needle Buckling/Stiffness Test Results

Description	Acupuncture Needle	**Specification**	0.30 * 25mm
Test date	*The factory will add.*	**Batch number**	002/05
Batch	150,000 pieces	**Test Basis**	GB/T 4342 -91(Chinese National Standard)

Inspection/Test records For The hardness Of Body part of the needles (at HV 0.2kg):

468, 472, 475, 470, 468, 465, 468, 470.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2002

Wujiang City Hua Xin Medical Appliance Company Limited
C/O Ms. Laura J. Thorne
Thorne Sales & Distributing, Incorporated
10 Westmont Road
Candler, North Carolina 28715

Re: K021095
Trade/Device Name: Holy Dragon Acupuncture Needles
Regulation Number: 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: March 15, 2002
Received: April 4, 2002

Dear Ms. Thorne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021095

Attachment B

STATEMENT OF INDICATIONS FOR USE

510(k) NUMBER: K021095

DEVICE NAME: Holy Dragon Acupuncture Needles

INDICATIONS FOR USE:

To pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021095